



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,551	11/27/2001	Jamie S. Henderson	498-269	8199

7590 12/27/2005

Ludomir A. Budzyn
HOFFMAN & BARON, LLP
6900 Jericho Turnpike
Syosset, NY 11791

EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
----------	--------------

3761

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,551	HENDERSON ET AL.	
	Examiner	Art Unit	
	Patricia M. Bianco	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-52,57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) 6-11,14-17 and 21-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,12,13,18-20,57 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-53, 57, & 58 have been considered but are moot in view of the new ground(s) of rejection.

Claim 3 was cancelled in the amendment filed 9/23/05. As a result, claims 1, 2, 4, 6-53, 57 & 58 remain pending and claims 6-11, 14-17, & 21-53 remain withdrawn to non-elected invention(s).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gianotti (5,993,483) in view of Popadiuk et al. (5,556,426). Gianotti discloses implantable stent, which may be used as an A-V shunt graft. The device comprises a tubular body having an interior surface or lumen for allowing fluid flow therethrough. The tubular body has longitudinal ribs extending generally straight and parallel along the longitudinal axis of the tubular body. The ribs are uncovered for direct contact with tissue. Gianotti discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the tubular body has a first end having a flow area larger than the flow area of the second end.

Popadiuk discloses an implantable tubular conduits, such as a an A-V shunt graft. The device comprises a tubular body (12) having an interior surface or lumen for allowing fluid flow therethrough. Ribs (14) extending from the surface. The ribs are uncovered for direct contact with tissue. Popadiuk discloses that the conduit may be a tapered graft; therefore, the graft will inherently have one end larger than the other end. Since applicant has not set forth any criticality, it would have been an obvious matter of design choice to make the tubular body of Gianotti tapered and have one end larger than the other as taught by Popadiuk, since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. In re Dailey, 149 USPQ 47 (CCPA 1976).

Claims 1, 2, 4, 12, 13, & 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianotti ('483) in view of Martakos et al. (6,416,537). Gianotti discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the tubular body has a tubular sleeve and that the device is made of PTFE.

Martakos discloses a medical device that can be used as a vascular graft for arteriovenous applications. The device comprises a tubular body (20) having an interior surface or lumen for allowing fluid flow therethrough. The tubular body and ridges are formed of a biocompatible material, which is generally a polymeric material and said material may be made of expanded PTFE. A sleeve (30) having ridges (40) or ribs extending from and being unitary with said sleeve. The ridges, being formed on/with the sleeve, are not coextensive with the body of the tube. The ridges extend longitudinally along the body, generally straight, and are spaced-apart. The ridges are uncovered for direct contact with tissue. With respect to claim 12, the ridges are adhered to the sleeve and therefore will inherently have a sealant material adjacent thereto. At the time of the invention, it would have been obvious to modify the device of Gianotti to be made of PTFE since it is a well known, preferred material in the art and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It would also have been obvious to modify the device of Gianotti to have a tubular sleeve portion as taught by Martakos as means for providing a sealant material to easily attach the ribs to the body.

Art Unit: 3761 .

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gianotti & Martakos as applied to claims 1, 2, 4, 12, 13, & 18-20 above, and further in view of Popadiuk ('426). Gianotti & Martakos discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the tubular body has a first end having a flow area larger than the flow area of the second end.

Popadiuk discloses an implantable tubular conduits, such as a an A-V shunt graft. The device comprises a tubular body (12) having an interior surface or lumen for allowing fluid flow therethrough. Ribs (14) extending from the surface. The ribs are uncovered for direct contact with tissue. Popadiuk discloses that the conduit may be a tapered graft; therefore, the graft will inherently have one end larger than the other end. Since applicant has not set forth any criticality, it would have been an obvious matter of design choice to make the tubular body of Gianotti tapered and have one end larger than the other as taught by Popadiuk, since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. In re Dailey, 149 USPQ 47 (CCPA 1976).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 21st, 2005

Patricia M Bianco
Primary Examiner
Art Unit 3761


PATRICIA BIANCO
PRIMARY EXAMINER